

## **II. REMARKS.**

### **A. Claim and Specification Status.**

Upon entry of this Amendment, claims 2, 3, and 6-41 are pending. Claims 2, 6-9 and 13-41 stand rejected under 35 U.S.C. §112, paragraph 1, for scope of enablement. Claims 2, 6-9 and 13-41 stand rejected under 35 U.S.C. §112, paragraph 2 as indefinite. Claims 2, 6-9, 11, 13-19, 22-26, 28, and 31-41 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,707,843 to *Monte*. Claims 20-23, 27, 29-30 and 40 stand rejected under 35 U.S.C. § 103(a) as obvious in light of U.S. Patent Nos. 5,707,843, 5,578,336 and 5,424,299, all to *Monte*. Claims 2, 6-9, 11, 13-19, 22-26, and 31-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,707,843 to *Monte*. Claims \_\_\_\_ are cancelled. Claims \_\_\_\_ are currently amended. The claims as amended traverse the Examiner's rejections. No new matter is submitted.

Applicant notes that there appears to be an error in the Office Action in that the Examiner has indicated that claim 3 has been cancelled. Specifically, the Office Action has stated that "This Office Action is a response to Applicant's amendment and response to the previous Office Action (mailed October 20, 2004), filed April 26, 2004 wherein claims 3-5 are cancelled; claims 2 and 6-41 have been amended."

The April 26, 2004 response filed by Applicant, on page 2, shows that claim 3, claims 6-24, claims 26-32, and claims 34-40 remain as originally presented. Applicant respectfully submits that these claims have never been amended and have never been cancelled, and remain pending as originally presented. Applicant respectfully requests that claims 3, 10, and 12 be examined in addition to the claims 2, 6-9, 11, and 13-41 that the Office Action states have already been examined on the merits.

### **B. Claim rejection under 112, first paragraph**

Claims 2, 6-9, and 13-41 stand rejected under 35 USC 112, first paragraph for scope of enablement. Specifically, the Examiner has stated that

the specification, while being enabling for the particular and specific agent such as a lactose-converting enzyme to be added into a particular food or cosmetic composition, employed in the claimed method herein, does not reasonably provide enablement for any substances or compounds represented by "an active" and " food or cosmetic composition", "composition is at or above a

temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition”, a lactose-converting active” and “a lactose-containing composition”, recited in the claims herein.

Those recitations, “an active” and “a food or cosmetic composition”, “composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition”, “a lactose-converting active” and “a lactose-containing composition”, as seen to be merely function language.

Applicant gratefully acknowledges that the Examiner has agreed that the specification is enabling for the particular and specific agent such as a lactose-converting enzyme to be added into a particular food or cosmetic composition, employed in the claimed method herein.

The Examiner states, at p. 4, that “Functional language at the point of novelty, as herein employed by Applicants, is admonished...,” implying that *the active itself* is at the point of novelty. In fact, however, the method of claim 2, for example, refers to a *method for adding a device to a food or cosmetic composition*, wherein the device *comprises* an active (emphasis added).

The method actually set forth in Claim 2 is, in fact, adequately supported by the specification as originally filed. For example, at page 6 of the specification as originally filed, an aspect of the invention is presented as “a *structure or device*, such as a tablet, capsule or overlay *including* an active... Preferably, *the active is included as part of a structure or device*, such as a tablet, capsule or overlay wherein at least enough of the active is protected, either by being coated, covered or otherwise protected, *to prevent the active from coming into direct contact with the composition* until the structure or device at least partially dissolves (emphasis added).

The method can therefore be employed with any active, as “active” is defined in the specification as originally filed. The active itself is described, at page 1 of the specification as originally filed, as “one or more biologically active substance(s), materials(s) or constituent(s) and includes enzymes, antibodies, vitamins or a combination thereof.” Applicant respectfully submits that support for the term “active” has been adequately provided, particularly in light of the fact that Claim 2 is actually directed to a method for adding a device to a food or cosmetic composition, wherein the device comprises an active.

Similarly, as to whether the specification provides enablement for substances or compounds represented by “a food or cosmetic composition”, Applicant respectfully submits

that, whatever food or cosmetic composition a practitioner might choose to use (provided, of course, that the food or cosmetic composition is as defined in the specification as originally filed), the practitioner may use the method as set forth in claim 2 to add a device to the food or cosmetic composition.

Applicant respectfully submits that “food or cosmetic composition” is adequately enabled at, for example, page 1 of the specification:

As used herein, the term ‘composition’ refers to any substance, intermediate, constituent or formula in which an active may be included to impart a beneficial effect, and includes foods, cosmetics and skin lotions. As used herein, the term ‘food’ or ‘foods’ means any foodstuff suitable for human or animal consumption, or intermediate composition or ingredient used to make a foodstuff, and includes liquids.

Again, applicant points out that Claim 2 is to a method for adding a device to a food or cosmetic composition, wherein the device comprises an active. Therefore, applicant respectfully traverses the need to describe the food or cosmetic composition any further than the ample description provided in the specification as originally filed.

As to whether the specification provides enablement for substances or compounds represented by “composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition”, Applicant respectfully submits that each active may have a temperature that would denature the particular active. However, one of ordinary skill in the art, given an active, may easily determine a temperature that would denature the active. Therefore, Applicant respectfully submits, the temperature is fully enabled for each active.

As to whether the specification provides enablement for substances or compounds represented by “a lactose-converting active,” Applicant respectfully submits that ample enablement is provided at, for example, page 2 of the specification as originally filed (“In one specific example, a lactose-converting enzyme (called lactase enzyme) may be added to a composition to convert lactose to another substance, such as a monosaccharide.”) Moreover, Applicant submits that Claim 2, for example, is directed to a method for *adding a device to* a food or cosmetic composition, wherein the device comprises an active. Applicant submits that further enablement is not necessary.

As to whether the specification provides enablement for substances or compounds represented by “a lactose-containing composition”, Applicant respectfully directs the Examiner’s

attention to page 2 of the specification as originally filed (“In one specific example, a lactose-converting enzyme (called lactase enzyme) may be added to a composition to convert lactose to another substance, such as a monosaccharide.” A plain reading of this sentence (among other sentences throughout the specification) indicates that the composition contains lactose. Therefore, a “lactose-containing composition” is described in the specification as originally filed.

Moreover, Applicant submits that Claim 2, for example, is directed to a method for *adding a device* to a food or cosmetic composition, wherein the device comprises an active. Applicant submits that further enablement of the particular lactose-containing composition is not necessary; all that is necessary for Claim 2 is that the composition be such that a device may be added to it.

For the foregoing reasons, Applicant respectfully requests that the rejection under 35 USC 112 be withdrawn and that the rejected claims be allowed and passed to issuance.

**C. Claim rejection under 112, second paragraph**

Claims 2, 6-9, and 13-41 stand rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner has stated that the recitation of “active” in claim 2 renders claims 2, 4-9, and 13-41 indefinite. The Examiner has also stated that the recitation “would” in claim 2 renders claims 2, 4-9, and 13-41 indefinite. Finally, the Examiner states that Claim 1 recites the limitation “the beneficial effect” which renders these4 claims indefinite.

Applicant respectfully traverses these rejections. When the term “active” is adequately defined and explained in the specification, its recitation in claim 2 cannot render dependent claims indefinite.

With respect to the word “would” within Claim 2, Applicant submits that the word “would” must be taken within the element as a whole. Claim 2 refers to a method that comprises, among other steps, adding the device to the composition while the composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition.” As stated above, one of ordinary skill in the art can determine a temperature that would denature the active for any particular active that may be provided. Accordingly, the temperature is not indefinite once the particular active to which a practitioner may wish to include within the device is determined.

Accordingly, Applicant respectfully submits that the phrase “a temperature that would denature the active” is not indefinite.

**D. Response to arguments of previous Office Action**

At page 8 of the Office Action, the Examiner maintains that, because claims are given their broadest reasonable interpretation, phrases such as “active” are not definite.

Applicant submits that the Examiner may have misunderstood Claim 2 to be directed to an active itself, or to a composition. Applicant submits that Claim 2 is actually directed to a method for adding a device to a food or cosmetic composition, not to an active or to a composition itself. Accordingly, Applicant submits that the description is adequate.

Applicant submits that the rejected terminology from the claims has been thoroughly enabled in the specification, and is not indefinite. However, even if it were not (and Applicant certainly does not admit that it is not), not every item mentioned in a claim must be thoroughly described: As the District of New Jersey has pointed out,

The patentee offers this analogy, which the court finds persuasive: "If one were to invent a new paper hole puncher, the claims would necessarily describe a location for positioning the paper, a punching die adapted to pierce the paper, and the like. But that would not make paper an element of the claim, such that one could freely knock off the hole puncher and sell it without liability for infringement as long as no actual piece of paper is packaged with the hole puncher." ...see also Robert C. Faber, Landis on Mechanics of Patent Claim Drafting (4th ed. 1999), Gilman Suppl. Markman Decl. Exh. 41, § 15, at III-2 ("The article to be worked on, the **workpiece**, need not be **defined in detail**, unless such a **description** is important to the functioning of the apparatus or made necessary by the prior art.")... The **workpiece** appears in the body of the claim, as it interacts with a claim element.") (Emphasis added).

SDS USA, Inc., V. Ken Specialties, Inc., 107 F. Supp. 2d 574 (D.N.J., 2000)

**E. Rejections Under 35 U.S.C. §§ 102 and 103.**

Applicant respectfully submits that the continued rejections under 35 U.S.C. §§ 102 and 103 are inappropriate. Applicant respectfully points out that, in the section of the Office Action entitled “Response to Argument,” pp. 8-9 of the Office Action, the Examiner has not responded to the arguments pertaining to the Claims Rejections under 102 and 103. For this reason,

Applicant respectfully reiterates the arguments presented in response to the previous Office Action.

Monte '843 does not teach, suggest or show, among other things, the addition of an active to a substance while the substance is at a temperature that would normally denature the active and, utilizing the invention, the active is not denatured. As explained in the Background and Summary of the Invention sections, this is a significant improvement over the prior art. (Applicant again notes that Monte is the inventor of the present application and thoroughly understands the difference between this invention and his prior inventions.) **In fact, the Examiner does not even assert in the Office Action that Monte teaches these steps or features. Also, As the Examiner recognizes, Monte does not expressly disclose providing a tablet including the active.**

Instead, the Examiner simply asserts that "It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a tablet including the active...." Apparently, the Examiner considers that a tablet to be taken internally as a food anticipates a tablet containing an active. Applicant points out, once again, that claim 2 is directed to a method for adding a device to a food or cosmetic composition, wherein the device comprises an active, the method comprising adding the device to the composition while the composition is at or above a temperature that would denature the active. Applicant respectfully questions whether the Examiner believes that the tablet in various embodiments of the present invention is to be heated and then ingested.

Finally, as stated in response to the previous Office Action, the specific sections of Monte '843 cited now by the Examiner are addressed below:

1. The abstract does not even address the temperature at which an active is added to a composition.
2. Column 1, lines 21-39 merely describe a prior art method and the deficiencies thereof. 140 degrees F is below the denaturing temperature of lactase enzyme. The same prior art example is recited on page 4, lines 14-23 of the present application.
3. Column 2, lines 7-10 appear to have nothing to do with the temperature at which the active is added to the composition.
4. Column 2, lines 18-49 do not mention adding an active to a composition while the composition is at a temperature that would normally denature the active.

5. Columns 5-6 teach away from the present invention. At column 5, ll. 28-35, it states, among other things, that “[h]eating the dairy product to a pasteurization or sterilization temperature after the enzyme composition is added is counterproductive in practicing the invention because enzymes are deactivated at pasteurization and sterilization temperatures.”

6. Column 1, line 63 - column 2, line 13 do not teach any aspect of the claimed method to make a composition. In fact, column 1, lines 63-67 teach the provision of “an improved food composition which can, after a dairy product has been pasteurized or sterilized, be combined with a dairy product to reduce the concentration of lactose in the dairy product. Hence, this expressly teaches away from the claimed invention.

In view of the comments above, Applicant submits that the rejections under 35 U.S.C. §§ 7102 and 103 are traversed.

#### **F. Double Patenting**

The Examiner has stated that the “A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground...”

Applicant respectfully requests that the double-patenting rejection be withdrawn, in light of the foregoing arguments. Applicant respectfully traverses the need for such a terminal disclaimer. However, Applicant respectfully reserves the right to file a terminal disclaimer upon allowance of one or more claims.

### **III. Conclusion.**

In view of the amendments and arguments herein, this Application is believed to be in condition for allowance and favorable action is requested. Applicant reserves the right to prosecute additional claims, including claims of broader scope, in a continuation application.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to **Deposit Account No. 19-3878**. Applicant further reserves the right to prosecute broader claims in this application or a continuation application.

The Examiner is invited to telephone the undersigned at the telephone number listed below if it would in any way advance prosecution of this case.

Respectfully submitted,

January 28, 2005

Date

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